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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/530,171

05/17/2005

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23460 7590 12/22/2008  
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EXAMINER

BRISTOL, LYNN ANNE

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

12/22/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/530,171 | <b>Applicant(s)</b><br>HIRAKAWA ET AL. |  |
|                              | <b>Examiner</b><br>LYNN BRISTOL      | <b>Art Unit</b><br>1643                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 12-35 and 42 is/are pending in the application.
- 4a) Of the above claim(s) 12-35 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 1, 12-35 and 42 are all the pending claims for this application.
2. Claim 1 was amended, Claims 3, 4 and 36-41 were cancelled and new Claim 42 was added in the Response of 7/18/08.

Newly submitted claim 42 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 1 is directed to an isolated antigen, Claims 12-30 and 33-35 are drawn to a ligand recognizing the antigen, and Claims 31, 32 and 42 are drawn to a method of treating a cancer with a pharmaceutical composition comprising the ligand.

Since applicant has received an action on the merits for the originally presented invention (isolated antigen), this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 42 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 12-35 and 42 are withdrawn from examination.
4. Claim 1 is the pending claim under examination.
5. Applicants' amendments to the claims have necessitated new grounds for rejection. This action is FINAL.

**Withdrawal of Rejections**

***Claim Rejections - 35 USC § 112, second paragraph***

6. The rejection of Claims 1, 3, 4 and 36-41 for the recitation “exposed on a surface of a cell of a solid tumor” is moot for the cancelled claims 3, 4 and 36-41 and withdrawn for claim 1 in view of the amendment to the claim to delete the phrase.

7. The rejection of Claims 3, 4 and 36-41 for the recitation "a cultured cancer cell" in Claims 3 and 4 because the recitation is a broadening limitation from Claim is moot for the cancelled claims.

***Claim Rejections - 35 USC § 112, first paragraph***

***Written Description (1)***

8. The rejection Claims 1, 3 and 4 (and Claims 36-41) under 35 U.S.C. 112, first paragraph, in lacking written support for any kind of cultured breast cancer cell and the solid tumor from which it is formed, and which cells express a part of the antigen on the cell surface and which comprises residues 600-1,960 of SEQ ID NO: 17 is moot for cancelled Claims 3, 4 and Claims 36-41 and withdrawn for Claim 1 in view of the amendment to the claim to delete the phrase.

***Written Description (2)***

9. The rejection of Claims 1, 3, 4 and 36-41 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claims encompass a genus of tumor antigens that are not described in the specification is moot

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for cancelled Claims 3, 4 and Claims 36-41 and withdrawn for Claim 1 in view of the amendment to the claim to delete the phrase.

***Written Description (3)***

10. The rejection of Claims 36-41 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claims encompass ranges for tumor antigen production or expression that are not described in the specification is moot for cancelled Claims 36-41.

***Claim Rejections - 35 USC § 102***

11. The rejection of Claims 1, 3 and 4 under 35 U.S.C. 102(b) as being anticipated by WO 01/75067 (HYSEQ, INC; published 10/11/2001; cited in the IDS of 12/21/05) as evidenced by Creighton et al. (Genome Biol. 4(7):R46 (2003)) is withdrawn.

The amendment of Claim 1 to recite that the antigen consists of residues 600-1,960 of SEQ ID NO:17 overcomes the rejection.

***New Grounds for Rejection***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

***Written Description***

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12. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As amended, the scope of Claim 1 has been changed from the original elected invention for “an antigen having a part which is exposed on the surface of a cell at the formation of a tumor mass” (see original Claim 1) to “an isolated antigen consisting of residues 600-1,960 of SEQ ID NO:17.”

Applicants have not shown that “the isolated antigen consisting of residues 600-1,960 of SEQ ID NO:17” is itself a tumor marker or a tumor associated antigen. The extent to which the specification defines the claimed antigen is that “the sequence of a C-terminal domain of the protein sequence [*NMMHC type 2*] is a sequence of the residue at position 600 to the residue at position 1,960 from the N-terminal of SEQ ID NO: 17 in the Sequence Listing (p. 3, lines 9-11); and “Examples of the sequence of a C-terminal domain of the protein of the present invention include a sequence of the residue at position 600 to the residue at position 1,960 from the N-terminal side of nmMHCA represented by SEQ ID NO: 17 in the Sequence Listing” (p. 7, lines 1-5). The specification and the evidence of record does not teach that the claimed sequence stretch would be found to be expressed in any cancer cell and that it alone would be used as an isolated antigen.

The specification does not appear to actually even contemplate the instant claimed invention.

***Conclusion***

13. No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LAB

/David J Blanchard/  
Primary Examiner, Art Unit 1643